REMARKS

This Amendment is responsive to the final Office Action mailed August 28, 2007 (hereinafter "Office Action"). By this Amendment, claims 1, 3, 5 & 11 are amended, claim 12 is cancelled, and independent claim 21 is added. No new matter is added.

Applicants wish to thank Examiner Mercier and Supervisory Patent Examiner Kishore for extending the courtesy of a telephonic interview on Eastern on Monday, November 26, 2007. During the Interview, Applicants explained several salient features of the invention to the Examiners. Although no agreement was reached with regard to the rejections, Applicants believe that progress was made.

Amendments to the Claims

Claim 1 is amended to incorporate the limitation on plasticizers found in claim 12, which has been cancelled. As suggested by the Examiners, claims 1 and 5 have been amended to clarify the components of the spherical coated capsule.

Claim 3 is amended to correct a typographical error that occurred during translation of the German language priority application.

Claim 11 is amended to recite a plasticiser content in the shell of " 15 - 20 % (m/m) based on the total solids content of the shell." Support for this limitation can be found throughout the specification, including paragraph [0060] and original claim 11.

New claim 21 is based on claim 1; however, the list of plasticizers found in claim 21 does not include sorbitol.

No new matter is added.

Claim Rejections -35 U.S.C. § 103(a)

In the Office Action, claims 1, 5-6, 11-12 and 18-19 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler") in view of U.S. Patent No. 6,200,603 issued to Rowe *et al.* (hereinafter "Rowe").

Claim 1

Prior to addressing the cited references, Applicants wish to review the claimed invention. As set forth in independent claim 1, the claimed invention is drawn to:

1. (currently amended) A spherical coated capsule comprising

(a) ~~a coating-free capsule having (i)~~ a liquid or viscous core ~~and (ii)~~,

(b) a ~~seamless solid~~ shell surrounding this core, and

(c) ~~(b)~~ a seamless, solid coating ~~surrounding~~ on said shell ~~coating-free capsule~~, wherein

- the diameter of the coated capsule is in the range of 5 - 9 mm,
- the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule,
- the diameter of the shell ~~coating-free capsule~~ is in the range of 3 - 7 mm,
- the thickness of the shell ~~of said coating-free capsule~~ is in the range of 20 -200 µm,
- the ratio of shell thickness to shell diameter ~~of said coating-free capsule~~ is in the range of 0.004:1 - 0.04:1 ,
- the shell ~~of said coating-free capsule~~ contains 70 - 90 % (m/m) gelatine or alginate and 10 - 30 % (m/m) plasticiser, based on the solids content of said shell, and
- the core has a flavouring content in the range of 1 - 100 % (m/m), based on the total mass of the core, wherein the plasticiser is selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof.

As noted in the specification, prior to the claimed invention, "it has been found to be disadvantageous that the majority of shells of ready-to-consume capsules available commercially are detectable as an unpleasant, rubbery, tough residue. Corresponding observations are made and found to be particularly negative especially in the case of larger filled capsules with diameter of about 4 mm," *see* Specification, paragraph [0005], subheading 1. In contrast to the prior art materials, the claimed spherical coated capsules (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky. The core liquid containing flavoring that is to be released or is released should give rise to a sensory effect with a substantial impact in the mouth, *see* Specification, paragraph [0005], subheading 2.

Thus, in contrast the claimed spherical coated capsules, the prior art capsules are either designed to release the core liquid after the capsule is swallowed (*e.g.* enteric coatings) or designed to release the active ingredients slowly in the oral cavity.

An important feature of the claimed invention is the ability to provide a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but also dissolves rapidly, does not stick to the teeth, and does not have a disturbing haptic effect in the mouth. Although the general class of coated capsules are well known in the art, it is equally well-known that there are abundant challenges remaining to develop coated capsules with specific properties. It is also well-known that small changes in amounts of ingredients can have a substantial and unpredictable result on the properties of the shell and the interaction of the shell with the core or the shell with any coating deposited thereon. Prior to the Applicants' development of the claimed invention, researchers had not successfully developed a shell with the properties of the claimed invention: a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but that dissolves rapidly once in the mouth, does not stick to the teeth, and does not have a disturbing mouthfeel. The Applicants were able to develop the claimed invention, which successfully provides these properties, using a unexpected combination of ingredients that is neither disclosed or suggested by the cited art, whether alone or in combination.

Turning now to the Stapler reference. Stapler is drawn to oral compositions in the form of microcapsules which reduce oral bacteria and provide long lasting breath protection, *see* Stapler, Abstract. The challenge addressed by the Stapler microcapsules was the development of a microcapsule that was capable of containing a core that included breath control agents and antimicrobials, *see* Stapler, col. 1, ln. 28-34 & 46-50. The solution to this problem was to include a small amount of breath control agents and antimicrobials in the shell material and to produce a core from a mixture of the breath control agents and antimicrobials and a organic diluent, *see* Stapler, col. 2, ln. 26-55; claim 1. Although Stapler discloses adding the same amount of breath control agent to the shell and the core, Stapler does not provide any relevant disclosure regarding the amounts of specific gelling agents and plasticizers that can be used in a microcapsule or the effect of varying the amount of gelling agents and plasticizers in the microcapsule, *see* Stapler, col. 2, ln. 10 – 24.

In fact, a review of Stapler demonstrates that there is no discussion of plasticizers in the entire reference. Stapler does disclose that a 70% aqueous solution of sorbitol is used in Examples 1-5; however, Stapler does not disclose whether the sorbitol is in the core or the shell. In fact, Stapler discloses that sweetening agents, which must include sorbitol, can be included in the core, *see* Stapler, col. 2, ln. 66-68. Thus, while Stapler may disclose specific capsules that include sorbitol (without disclosing whether the sorbitol is in the shell or the core), there is no true disclosure or teaching regarding plasticizers. This would be particularly true for any plasticizer other than sorbitol.

Rowe is drawn to a coated capsule comprising a gelatin shell with a flavored coating, *see* Rowe, Abstract. The coated capsules disclosed in Rowe are "intended for swallowing substantially intact, for release of the contents only when the capsule has reached the stomach," *see* Rowe, col. 1, ln. 16-18. Rowe specifically states that "the capsule fill is not released until the capsule shell is broken down in the stomach," *see* Rowe at col. 1, ln. 42-44. Rowe discloses substantially higher content of plasticizers than that of the claimed invention, *see* Rowe, col. 1, ln. 66 – col. 2, ln. 62 and col. 3, ln. 55 – col. 4, ln. 23.

The Stapler reference neither discloses microcapsules with a coating, nor does it disclose the claimed plasticizer content of 10 – 30 % (m/m). In fact, the Stapler disclosure is very limited with regard to how much gelling agent and plasticizer should be present in a microcapsule or the impact of varying the types and amounts of gelling agent and plasticizer. A person of ordinary skill in the art would understand that there would be different minimum thicknesses for the shell depending on the specific gelling agent, the specific plasticizer(s), and the relative amounts of each. The lack of guidance regarding these interactions clearly limits the usefulness of the Stapler reference with regard to the shell thickness and amounts and types of gelling agents and plasticizers capable of producing a stable shell having the claimed thickness and thickness to diameter ratio. The true teaching in Stapler is to use small amount of breath control agents and antimicrobials in the shell material and a core that includes a mixture of the breath control agents and antimicrobials and a organic diluent

Because Stapler does not provide useful information about the relevant amount of gelling agents and plasticizers, a person of ordinary skill in the art would look to the Rowe reference for guidance. In contrast to Stapler, the Rowe reference provides an extensive

discussion of a gelling agent (gelatin), specific amounts of plasticisers, and amounts of each that are useful in for forming a shell material, *see* Rowe, col. 1, ln. 66 – col. 2, ln. 62 and col. 3, ln. 55 – col. 4, ln. 23. An accurate analysis of Rowe demonstrates that Rowe clearly teaches away from the claimed amounts of plasticizers and gelatin or alginate, and clearly teaches away from the claimed shell thickness.

The Rowe disclosure provides preferred amounts of specific plasticizers and preferred plasticizer-to-gelatin ratios. The "typical minimum levels of glycerin and sorbitol" are 17.7 wt-% and 16.7 wt-%, respectively, *see* Rowe, col. 2, ln. 16-33, while the "typical maximum amounts" of glycerin and sorbitol are, 29.3 wt-% and 38.6 wt-% respectively, *see* Rowe, col. 2, ln. 49-61. Rowe expressly states that the "total plasticizer" in the minimum and maximum embodiments is 34.4 wt-% and 57.9 wt-%, respectively, *see* Rowe, col. 2, ln. 31 & 60. This is well outside the 10 – 30 wt-% plasticizer of claim 1. It is also substantially different from the 15 - 20 % wt-% plasticizer of claim 11. Clearly, the combination of Rowe and Stapler does not disclose or suggest this element of the claimed invention, which results in substantially improved capsule properties, *i.e.* capsules that (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky..

The Office Action also states that Rowe expressly teaches toward the claimed shell thickness of 20 -200μm. The Office Action cites the following statement from Rowe:

> It is of course desirable to minimise [*sic*] the quantity of shell material in the coated product, and in this respect it is recognised [*sic*] that with a sufficiently stable interface and bond between the coating and shell, the coating will serve to reinforce the shell, and the shell to effectively seal the coating. Thus, if the shell thickness can be reduced such that its entire thickness is effectively bonded to the coating, then the resultant product will include a bare minimum of shell material.

Rowe, col. 3, ln. 27-35.

Like all disclosures in any reference, this disclosure must be interpreted in the context of the entire disclosure. This is particularly true where, as here, relative terms are used. In this case, it is apparent that a "thin" shell to one inventor may not necessarily be a "thin" shell to another.

Rowe does not directly specify what would by considered a "bare minimum of shell material" for purposes of that disclosure. However, the Example provide insight into what Rowe considers an exemplary breath freshener, with a liquid core, *see* Rowe, col. 3, ln. 55 –

col. 4, ln. 32. In the Example, the fill weight is 160 mg, the shell weight is 100 mg, and the coating weight is 277 mg, *see* Rowe, col. 3, ln. 60 – col. 4 , ln. 23. Thus, the shell weight accounts for approximately 38.5 wt-% (100 mg / 260 mg * 100%) of the uncoated capsule.

In the claimed invention, the shell accounts for 11 wt-% or less of the coating-free capsule, *see* Specification, paragraph [0143] & table following paragraph [0129]. Clearly, what Rowe considers to be a "bare minimum of shell material," *i.e.* shell comprising 38.5 wt-% of the uncoated capsule, is substantially more than that of the claimed invention, *i.e.* shell comprising 11 wt-% or less of the coating free capsule. A person of ordinary skill in the art would understand that Rowe considered approximately 38.5 wt-% shell to be a "bare minimum of shell." The logical reason is that Rowe was not able to produce thinner shells because Rowe had not discovered the claimed mixture of plasticizer and gelatine or alginate.

Thus, the combination of Rowe and Stapler does not disclose or suggest the claimed spherical coated capsules with (i) the specified amounts of plasticizer and gelatine or alginate, (ii) the claimed shell thickness and ratio of the shell thickness to the coating free capsule diameter, or (iii) the combination of both. Furthermore, Rowe expressly teaches away from the claimed amount of plasticizer and the claimed thickness. Thus, there would be no expectation of success for creating spherical coated capsules having the claimed properties and dimensions using the combination of Rowe and Stapler. Finally, because Rowe teaches away from the claimed invention and Stapler provides no relevant teaching, there would be no motivation to combine the reference in a manner that would result in the claimed invention.

Applicants reiterate that page 3 of the Office Action includes a significant error with respect to the rejection based on the combination of Stapler and Rowe. It is the abstract of Matthews, not Rowe, that discloses "the finished capsule shell formulation comprises 65-70% gelatin, 22-25% glycerin and 8-10% water." Thus, this disclosure is not relevant to the rejection based on Stapler and Rowe.

In the Office Action, claims 2-4, 7-10, 13-17 & 20 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler") in view of U.S. Patent No. 6,200,603 issued to Rowe *et al.* (hereinafter "Rowe") in view of some combination of U.S. Patent No. 4,816,259 issued to Matthews *et al.* (hereinafter "Matthews"), U.S. Patent No. 6,770,311 issued to Alamian *et al.* (hereinafter "Alamian"), U.S.

Patent No. 5,378,131 issued to Greenberg *et al.* (hereinafter "Greenberg "), U.S. Patent No. 5,342,626 issued to Winston, Jr., *et al.* (hereinafter "Winston") and U.S. Patent No. 4,888,140 issued to Schlameus *et al.* (hereinafter "Schlameus"). Applicants now address these references.

Matthews discloses ***enteric*** gelatine microcapsules with a gelatine content of 70 % (m/m – including water) and multiple coating layers. Matthews clearly teaches away from the claimed thickness. Matthews discloses:

> The capsules must be manufactured in such a way to provide a full and continuous seal at the time of manufacture. The gelatin film must be of adequate thickness to provide a minimum of 0.018" dry wall thickness.

Matthews, col. 4, ln. 14-18 (*emphasis added*).

A thickness of 0.018" converts to 457 microns in thickness. This is substantially thicker than the claimed 20-200 microns. Read in context, a person of ordinary skill in the art would understand that the shell must be more than 450 microns in order to provide the capsules with a "full and continuous seal at the time of manufacture." Quite simply, Matthews teaches that capsules must have a shell more than twice as thick as that claimed in order to be stable. This clearly does not disclose or suggest the claimed invention, clearly teaches away from the claimed invention and clearly would not provide a person of ordinary skill in the art with a reasonable expectation of success.

Matthews also describes that the microcapsule shell composition is specifically adapted to the composition of the "subcoating" also disclosed in Matthews. Applicants note that Matthews does not describe or suggest any alternative shell compositions. Thus, for a skilled person not relying on hindsight, Matthews would have only disclosed that a shell material composition has to be maintained when used in combination with a specific "subcoating." Thus, Matthews does not lead the skilled person to making the present invention.

Further, if the skilled person would have tried to produce hard gelatine microcapsules based on the Matthews reference they would have been instructed by this reference to increase the sugar content of the shell material. Thus, it would not have been obvious to provide a high gelatine content or increase the gelatine content. Furthermore, the skilled person would not have had any chance to further contemplate the specific sizes mentioned in claim 1 of the

pending application. And indeed the special difficulties in producing thin-walled microcapsules described on pages 8 and 9 of the present application would have deterred the skilled person from testing these dimensions. Thus, the skilled person would not have contemplated the subject matter of pending claim **1** when considering the Matthews reference.

According to the Examiner, Alamian discloses that a skilled person would contemplate the use of gelatine, fish gelatine etc. and alginate for the production of microcapsules. However, the capsules described by Alamian are explicitly said to be caviar replacements. It is well-known that caviar is sticky. Thus, when trying to produce non-sticky microcapsules, the skilled person would not have contemplated the use of the materials mentioned in the Alamian reference since he would have to believe that these materials would render the microcapsules sticking to teeth, tongue etc.

The Examiner cites Greenberg to establish that the skilled person would have contemplated using the flavours mentioned in pending claims **10** and **14** in the production of microcapsules. This document is simply not relevant because it does not effect novelty and inventiveness of pending claim **1**.

Winston describes compositions for capsules and encapsulation processes. However, Winston does not disclose that the materials would be any useful in the production of microcapsules. Thus, we believe the document is not relevant for assessing novelty and inventiveness of the present invention.

Schlameus discloses a method for producing round, filled microcapsules. However, Schlameus does not disclose providing a coating on the microcapsules. In addition, Schlameus does not provide any indication regarding the stickiness properties of the microcapsules. It is thus our impression that the document is just general prior art and not any relevant for assessing novelty or inventiveness of the present set of claims.

New Claim 21

Claim 21 is substantively similar to claim 1, with the exception that sorbitol is not one of the plasticizers claimed. As noted previously, a review of Stapler demonstrates that there is no discussion of plasticizers in the entire reference. While Stapler does disclose that a 70% aqueous solution of sorbitol is used in Examples 1-5, Stapler does not disclose whether the

sorbitol is in the core or the shell. However, Stapler specifically discloses that sweetening agents, which must include sorbitol, can be included in the core, *see* Stapler, col. 2, ln. 66-68. Thus, while Stapler may disclose specific compositions including sorbitol (but not whether the sorbitol is in the shell or the core), there is no true disclosure or teaching regarding the use of any plasticizer, particularly any plasticizer other than sorbitol.

Stapler discloses a much thinner shell than the other cited references. A person of ordinary skill in the art would understand that such thin shells required no plasticizer at all or sorbitol. Thus, if Stapler provides any teaching about plasticizers, Stapler teaches away from the use of plasticizers other than sorbitol. Clearly, there would be no motivation to combine Stapler with any reference that included a plasticizer other than sorbitol and clearly there would be not reasonable expectation of success for forming the spherical capsules of the claimed invention.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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